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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,434

02/15/2005

Rene Djurup

DJURUP1

4128

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EXAMINER

GUDIBANDE, SATYANARAYAN R

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

02/26/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,434	<b>Applicant(s)</b> DJURUP ET AL.	
	<b>Examiner</b> SATYANARAYANA R. GUDIBANDE	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,27-35,37,38,40,53,54,57,58,73 and 80-136 is/are pending in the application.
- 4a) Of the above claim(s) 57,58,80 and 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 27-35, 37, 38, 40, 53, 54, 73 and 82-136 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |



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### **DETAILED ACTION**

As per the petition granted on 8/27/09 (mailed date) the requirement to comply with the "sequence compliance" has been removed and the final action mailed on 6/18/09 has been vacated.

#### ***Election/Restrictions***

Applicant's election without traverse of group I invention (claims 1, 27-40, 53 and 73) and SEQ ID NO. 595 as species in the reply filed on 4/30/07 was acknowledged in the office action dated 6/19/07.

Applicant's amendments to claims submitted on 3/19/09 has been acknowledged.

Prior art search indicated that the elected species SEQ ID NO: 595 is free of art. The search could not be extended as the claim 1 as recited is indefinite under 35 USC 112, 2<sup>nd</sup> paragraph as set forth below.

Claims 1, 27-35, 37, 38, 40, 53, 54, 57, 58, 73 and 80-136 are pending.

Claims 57, 58, 80 and 81 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/30/07.

Claims 2-26, 36, 39, 41-52, 55, 56, 59-72 and 74-79 have been canceled.

Claims 82-136 have been added as new claims.

Claims 1, 27-35, 37, 38, 40, 53, 54, 73 and 82-136 are examined on the merit.

Any objections and/or rejections made in the office action dated 12/23/08 and not specifically discussed in original or modified form here are considered withdrawn.

***Allowable Subject Matter***

Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 102***

Applicant's arguments see pages 11 and 12, filed 3/19/09, with respect to claims 1, 36, 53, 73-75 and 77 have been fully considered and are persuasive. The rejection of claims 1, 36, 53, 73-75 and 77 has been withdrawn.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1, 53, 54 and 73 has been withdrawn in view of the amendments made to claim 1 that has been rejected under 35 USC 112, 2<sup>nd</sup> paragraph as set forth below. Upon further amendments to claims by applicants, the office may reinstate the withdrawn rejection.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

Applicant's arguments, see page 15, filed 3/19/09, with respect to the rejection(s) of claim(s) 1 under 35 USC § 112, 2<sup>nd</sup> paragraph, have been fully considered and are persuasive.

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Therefore, the rejection has been withdrawn. New ground(s) of rejection is made in view of amendments to claim 1.

*New grounds of rejections*

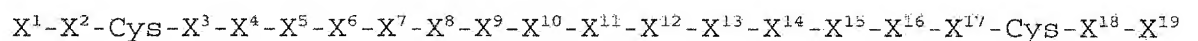
***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 27-35, 37, 38, 40, 53, 54, 73 and 82-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites following formula for a peptide:



The variable 'X4' has not been defined in the claim as recited. It is unclear from the claim as presented the nature of the amino acids the variable X4 correspond to.

2. Claims 1, 27-35, 37, 38, 40, 53, 54, 73 and 82-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the variable "X1 is Arg, Lys or a peptide consisting of 2-5 amino acids". Claim 1 further recites as a part of the proviso that "(a) X1 is amino acids 1-5 of SEQ ID

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NOs: 595, 600, 605 or 606". It is unclear from the 'condition (a)' as recited in the claim whether applicants imply peptide that corresponds to positions 1-5 of N-terminus or C-terminus of SEQ ID NOs: 595, 600, 605 or 606, or any of the 1-5 amino acids of SEQ ID NO: 595, 600, 605 or 606, or any 1-5 amino acid segments of SEQ ID NOs: 595, 600, 605 or 606. The claim as recited is also unclear because it recites the size of the peptide fragment as "2-5 amino acids" at one place and "1-5 amino acids" in the same claim for the same variable X1.

3. Claims 82, 87 and 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 82 recites a limitation "X1 is amino acids 1-5 of SEQ ID NO: 5. The SEQ ID NO: 5 of the instant case is a tetra-peptide corresponding to the sequence "Arg Gln Phe Gln". It is unclear from the claim as recited how a peptide which has only 4 amino acids in its sequence could meet the limitation that requires 5 amino acid residues.

4. Claim 103 recites the limitation "X4 is not Ala" in line 2. There is insufficient antecedent basis for this limitation in the claim. The variable 'X4' is not defined in the instant claim 1.

5. Claim 105 recites the limitation "X4 is not Ala" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. The variable X4 is not defined in the instant claim 1.

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6. Claim 106 recites the limitation "X4 is not Ser" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. The variable X4 is not defined in the instant claim 1.

7. Claims 112 and 113 recites the limitation "X4 is Ala, Gly, Ser, Thr or Met" and "X4 is Gly" respectively in lines 1-2 and 1 respectively. There is insufficient antecedent basis for this limitation in the claim. The variable X4 is not defined in the instant claim 1.

8. Claims 27, 28, 30-32, 35 and 40 recites sequences that contain 'proline' in "X1" variable, i.e., in position 1-5 at the N-terminus. The sequences does not contain Glutamine (Q or Gln) in position 19 as required by the proviso of claim 1 from which claims 27, 28, 30-32, 35 and 40 depend from. Hence, there is insufficient antecedent basis for the sequences recited in the claims 27, 28, 30-32, 35 and 40 in the base claim.

***Claim Rejections - 35 USC § 112 (Written description/New matter)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

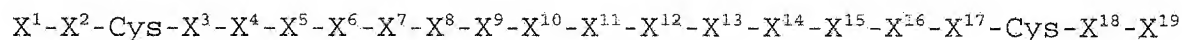
Claims 1, 27-35, 37, 38, 40, 53, 54, 73 and 82-136 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably



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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant invention, applicants claim a peptide having a sequence of at most 44 amino acid residues comprising the formula:



wherein, variable X1 to X3 and X5 to X19 are as recited in the claims and further recites a proviso: that when X1 includes Pro, then X19 is Gln, and wherein at least one of the following conditions applies:

(a) X1 is amino acids 1-5 of SEQ ID N0: 595, 600, 605 or 606; X1 is one of SEQ ID NOs:607, 608, 609, 610 or 612; or X1 is Arg or Lys; or

(b) X19 is not Gly, Ala or Ser.

Factors to be considered in making the determination as to whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing include:

- a. Actual reduction to practice;
- b. Disclosure of drawings or structural chemical formulas;
- c. Sufficient relevant identifying characteristics such as:
  - i. Complete structure,
  - ii. Partial structure,
  - iii. Physical and/or chemical properties or
  - iv. Functional characteristics when coupled with a known or disclosed correlation between function and structure;
- d. Method of making the claimed invention;
- e. Level of skill and knowledge in the art and
- f. Predictability in the art.

While all of these factors are considered, a sufficient number for a *prima facie* case are discussed below.

In the instant claim 1, the variable X4 is not defined as what amino acid residues correspond to X4. The lack of a description for the variable X4 renders the structure or the amino acid composition of the peptide recited indefinite.

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Claim 1 further recites as a part of the proviso that “(a) X1 is amino acids 1-5 of SEQ ID NOs: 595, 600, 605 or 606”. It is unclear from the ‘condition (a)’ as recited in the claim whether applicants imply peptide that corresponds to positions 1-5 of N-terminus or C-terminus of SEQ ID NOs: 595, 600, 605 or 606, or any of the 1-5 amino acids of SEQ ID NO: 595, 600, 605 or 606, or any 1-5 amino acid segments of SEQ ID NOs: 595, 600, 605 or 606. The claim as recited is also unclear because it recites the size of the peptide fragment as “2-5 amino acids” at one place and “1-5 amino acids” in the same claim for the same variable X1. The specification as disclosed does not support the size of the peptide at the N-terminus or C-terminus to be 1-5 amino acids length (also it is essential to have at least two or more amino acids to be identified as a peptide). If the claim as recited interpreted as any 1-5 amino acid residues of SEQ ID NOs: 595, 600, 605 or 606, then the instant specification lacks support for such an interpretation to support the claims as recited commensurate with the scope of the claims.

Claim 82 recite a limitation “X1 is amino acids 1-5 of SEQ ID NO: 5. The SEQ ID NO: 5 of the instant case is a tetra-peptide corresponding to the sequence “Arg Gln Phe Gln”. It is unclear from the claim as recited how a peptide which has only 4 amino acids in its sequence could meet the limitation that requires 5 amino acid residues. The specification and the sequence listing as disclosed does not adequately support the invention as recited in the instant claims.

### *New matter rejection*

Instant claim 1 recites the following proviso: “that when X1 includes Pro, then X19 is Gln, and wherein at least one of the following ‘conditions’ applies:

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(a) X1 is amino acids 1-5 of SEQ ID NO: 595, 600, 605 or 606; X1 is one of SEQ ID NOs: 607, 608, 609, 610 or 612; or X1 is Arg or Lys; or

(b) X19 is not Gly, Ala or Ser”.

The specification as disclosed support the invention as claimed the proviso “when X1 includes Pro, then X19 is Gln”. Additional conditions attached to the proviso such as X1 is one of SEQ ID NOs: 607, 608, 609, 610 or 612; or X1 is Arg are presented as preferred embodiments (page 12, lines 6-9). The above condition for the variable X1 is presented as a preferred embodiment and not as a preferred condition as part of the originally disclosed and recited proviso that the claim must satisfy as a requirement.

There is no literal support for the condition that “X1 is amino acids 1-5 of SEQ ID NO: 595, 600, 605 or 606”. The specification does not support the phrase “X1 is amino acids 1-5 of SEQ ID NO: 595, 600, 605 or 606”. The above mentioned ‘condition’ as recited lends itself to several interpretations such as: i) Peptide that corresponds to positions 1-5 of SEQ ID NOs: 595, 600, 605 or 606, or ii) any of the 1-5 amino acid residues of SEQ ID NO: 595, 600, 605 or 606, or iii) any 1-5 amino acid segments of SEQ ID NOs: 595, 600, 605 or 606, or iv) 1-5 amino acids of N-terminus of SEQ ID NOs: 595, 600, 605 or 606. Each of the peptides SEQ ID NOs: 595, 600, 605 or 606 are 25-mer in length and the number of possible ways that the 1-5 amino acids of the peptides SEQ ID NOs: 595, 600, 605 or 606 used as per the aforementioned alternate interpretations presented would be innumerable. The condition as recited not only lacks support in the specification, it fails to indicate which 1-5 amino acid residues of the above peptides are present as a variable X1 in the above formula.

By reciting the condition “X1 is amino acids 1-5 of SEQ ID NO: 595, 600, 605 or 606; X1 is one of SEQ ID NOs: 607, 608, 609, 610 or 612” and as presented in the instant claims applicants are carving out a subgenera of innumerable peptide sequences from amino acid residues or segments of the disclosed sequences for which there is inadequate disclosure support in the instant specification as illustrated above.

The condition “b) X19 is not Gly, Ala or Ser” also does not have literal or implied support in the instant specification with the proviso as recited in the instant claims. In the instant claims ‘when X1 includes Pro, then X19 is Gln’ is satisfied by SEQ ID NOs: 601 and 602 (instant claims 33 and 34 wherein X19 is ‘Gln’). Hence the condition “b) X19 is not Gly, Ala or Ser” applies but it is not a required condition as recited in claims 33 and 34 and the SEQ ID NOs: 601 and 602 satisfy the originally presented proviso ‘when X1 includes Pro, then X19 is Gln’.

Hence the claim as amended with the incorporation of the additional conditions to the proviso as illustrated above lacks support in the in the instant specification and hence constitute new matter.

### ***Conclusion***

Applicant's amendment to claim 1 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYANARAYANA R. GUDIBANDE whose telephone number is (571)272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/  
Examiner, Art Unit 1654

/Andrew D Kosar/  
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